

REMARKS

This Amendment and these remarks are being submitted in response to the Office Action mailed in this application on November 15, 2007. Claim 1 has been amended, and claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 remain pending in this application. Reconsideration of this application is respectfully requested in view of the above amendment and further in view of the following remarks.

Claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,494,852 (Barak, et al.) in view of U.S. Patent No. 6,589,194 (Calderon, et al.). Applicants respectfully traverse this rejection.

As previously discussed, Barak, et al. is directed to a device in which the thickness of the sleeve is reduced by providing interconnected compartments within each cell. The approach Barak, et al. have taken to making the device portable is to focus on reducing the thickness of the sleeve so that a reduced volume of air is needed to apply a suitable pressure to the limb. Barak, et al. have not been concerned with reducing the number of cells by identifying which cells are instrumental to the operation of the device. Moreover, the device of Barak, et al. includes one or more cells applied to the thigh. Applicants' claimed invention focuses on providing cells below the knee of the patient in order to provide effective treatment to the patient. Barak, et al. suggests that the number of cells can vary, but says nothing concerning the positions of those cells. Barak, et al. presents the device as including a thigh cuff. (See, for example, Figs. 1 and 2.) Given that Barak, et al. is concerned with making the device portable, and this is done by reducing the thickness of the sleeve so that a reduced volume of air is needed to apply pressure, it follows that if Barak, et al. believed the device would be effective without the presence of a thigh cuff, it would have been eliminated. It is not. Thus, from reading Barak, et al., one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device. If Barak, et al. would have believed otherwise, the device would have ended below the knee.

It is asserted in the Action that Barak, et al. teaches that it would have been obvious to limit the Barak, et al. device to include only a below the knee leg cuff and a foot cuff like the device in Calderon, et al. However, Barak, et al. does not teach that

treatment only below the knee is effective. The Barak, et al. device, for use on the leg, has a thigh cuff and a lower leg cuff. It is nowhere suggested that the thigh cuff can be eliminated. Moreover, the cells in Barak, et al. are independently controllable. Consequently, if the user wanted to treat only below the knee, it would be possible to use the full sleeve with thigh and lower leg cuff to do so merely by programming the controller to inflate only the lower leg cells. The thigh cuff would still be present. Barak, et al., however, does not suggest this. In fact, the opposite is taught. From the passage at column 6, line 63, through column 7, line 4, it is apparent that for a sleeve with a thigh and lower leg cuff with six cells, the control unit operates as shown in Fig. 7. This involves all the cells. There is no suggestion in Barak, et al. that some of the cells need not operate.

The Action relies on the passage at column 4, lines 14 to 15, which states that the invention can be used on “a part of a leg”. Applicants submit that the device shown in Figs. 1 and 2 of Barak, et al. *is* being used on a part of a leg in that the cuffs do not cover the knee, the ankle, or the upper thigh. The statement is therefore consistent with the device shown by Barak, et al. in Figs. 1 and 2 which includes a thigh cuff. The Examiner’s attention is further drawn to the description of the prior art in Barak, et al. At column 1, lines 34 to 35, the prior art devices are described as “big and ungainly”, and they are said to “restrict[s] the movement of the limb it encompasses”. This passage suggest that the prior art devices are used on the whole leg and, taken in this context, the device of Barak, et al., as shown in Figs. 1 and 2, is used on part of a leg. One of ordinary skill in the art, reading the passage at column 4, lines 14 to 15, therefore would not be motivated to eliminate the thigh cuff of Barak, et al.

The Action also relies on the passage in Barak, et al., at column 10, lines 34 to 35, which states that “[T]he number of cells in the sleeve can vary, according to desired treatments” (emphasis added). In the context of Barak, et al., the word “cell” is used to describe the compartments or bladders in each cuff. See, for instance, Fig. 2 where the cells are labeled **2**. Further, see column 4, lines 25 to 29, where it is explained, “The sleeve **1** has an inner and outer surface composed of a durable flexible material and is divided into a plurality of cells **2** along its length and each cell is connected to the control unit **3**...” The passage at column 10, lines 34 to 35, is therefore saying that each cuff

can have any number of *cells*. It does not say that the number of **cuffs** can vary. It certainly does not say that the thigh cuff can be eliminated. Contrast this passage to Applicants' claims which specify that the device consists of a leg cuff and a foot cuff, the leg cuff consists of only three cells, and those three cells have stated positions. Barak, et al. is saying that any number is appropriate and gives no guidance on what is most effective.

Moreover, Applicants' claims now also require that the leg cuff consists of only three cells with stated positions, and that those three cells are undivided. A significant difference between the cells of the claimed invention and those of Barak, et al., is that the cells of Barak, et al., are divided into longitudinal compartments which give the fluted profile on inflation as shown in Figure 4B of Barak, et al. Cells in the instant application are shown as undivided in Figure 3 and it is clear from the language already in claim 1 that each cell wraps around the limb and so is at least as large as the circumference of the limb.

Barak, et al., on the other hand, shows in Figures 1, 2, 3, 4A and 4B that, although each cell wraps around the limb, it is divided into intra cell compartments. Claim 1 of Barak, et al., for example, expresses this as the cells including at least three intra-cell compartments (claim 1), each compartment being elongated along a long axis and being substantially rectangular in shape. At column 4, lines 47 onwards, the cells are said to be subdivided into a plurality of longitudinal compartments 7, and those compartments in a given cell are confluent due to perforations in the seams between the compartments so that all the compartments in a cell are inflated or deflated simultaneously. This is most readily seen in Figures 4A and 4B. By contrast, the cells in the claimed invention are undivided so that the cell, when inflated, presents a smooth surface to the limb of the patient. The cells of Barak, et al., when inflated, present a fluted surface or a series of longitudinal peaks and troughs to the limb of the patient. An advantage of the smooth surface of the claimed invention is that the smooth surface applies an even compression to the limb and is more likely to apply that compression to the veins in the patient's limb. With the divided cells of Barak, et al., it is a matter of chance whether the compression applied to the limb by a peak in the inflation surface coincides with a vein underlying the patient's skin. The chances of applying effective

compression with the device of Barak, et al., are therefore much more hit and miss than with the undivided cells of the claimed invention.

Next, there is a very large gap between the passages cited in the Action and the conclusion that one of ordinary skill would find it obvious to combine Barak, et al., and Calderon, et al., to treat the lower limb. Barak, et al., gives no indication that such a device would be effective. Moreover, the teaching of Barak, et al., overall is that the sleeve has both a thigh and a lower leg cuff. Barak, et al., does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device. Thus, to arrive at the claimed invention, one of ordinary skill would not only have to eliminate the thigh cuff of Barak, et al., but he would also have to take away the compartments in each cell and eliminate the foot pump of Calderon. The Barak, et al., disclosure teaches that the compartments are essential to the invention. There is therefore no incentive to make the omissions that are necessary to arrive at the claimed invention when starting from Barak, et al.

Barak, et al. refers at column 1, line 65, through column 2, line 7, to prior art devices of the type that use a foot pump like that used by Calderon, et al. Barak, et al., however, teaches that focusing on the pump is a mistake and it was this focus that meant that no major breakthroughs in terms of the size of the sleeve/pump unit, its power source or mobility during use, were accomplished. Barak, et al., teaches that what one of ordinary skill should be doing is improving the use of the pumped air. These statements by Barak, et al., concerning foot pumps, would not motivate one of ordinary skill to combine the teachings of Calderon, et al., with those of Barak, et al. especially since Barak, et al. tells one of ordinary skill that no breakthroughs can be made in this way. This disincentive, coupled with the other disincentives in Barak, et al. for eliminating the thigh cuff, mean that one of ordinary skill would not make the combination suggested in the rejection.

The Action further relies on the very general statement in Barak, et al. that - "Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention." This very general statement would not suggest to one of ordinary skill

that the thigh cuff of the leg device could be omitted. Rather, one of ordinary skill would realize that many patents include this general statement and give the statement no weight.

With respect to claims 8 and 20, these claims feature a sock interposed between the device and the patient. Calderon, et al., at column 2, lines 65 to 67, states that "Related objects include ... avoiding the need for accessories such as additional wraps, straps, stockings or sandals". Thus, while Calderon, et al. accepts that a sock may be present, its aim is to avoid them. Claims 8 and 20 are not, therefore, obvious over a combination of Barak, et al. and Calderon, et al.

At least for these reasons, Applicants request that this rejection be withdrawn.

In view of the foregoing, entry of this Amendment, reconsideration of the application, and allowance of the application with claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20, are all respectfully requested.

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
100 Headquarters Park Drive  
Skillman, NJ 08558

/John M. Kilcoyne/  
John M. Kilcoyne  
Attorney for Applicants  
Reg. No. 33,100  
(908) 904-2372

Date: February 15, 2008